

REMARKS/ARGUMENTS

Claims 6 – 9, 11, 13 – 17, and 31 – 44 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over the combination of previously cited U.S. Patent No. 5,089,270 to Hampton et al. and newly cited U.S. Patent No. 3,409,570 to Dempski et al. Claims 18 – 20 and 45 – 47 have been rejected as being unpatentable over the combination of Hampton, Dempski, and Hoover.

Hampton describes a multi-colored tablet that is coated with a clear coating. The multi-coloration is achieved by combining a first powder material containing a first coloring agent with a second powder material containing a second coloring agent. The two powders are compressed to form a solid tablet having a demarcation line between the first material and the second material. The two-colored tablet is subsequently coated with a clear gelatin layer through which the color components are visible. The gelatin layer is clear and is not multi-colored. The two color sections comprise the core of the tablet and are not part of the coating.

Dempski generally describes a method and dye for color stabilizing a film coating composition on a tablet or pill so that the colored film coating resists discoloration or fading when exposed to sunlight or ultraviolet light. The Office Action alleges that it would have been obvious to incorporate the dye coating material stabilization methods as taught in Dempski with the bi-layered, two-colored tablet of Hampton to produce the claimed invention.

In order to establish a *prima facie* case of obviousness, three basic criteria must be met: 1) the reference(s) must teach or suggest all the claim limitations 2) there must be some suggestion to modify the references; and 3) there must be some reasonable expectation of success. The Office has failed to establish a *prima facie* case of obviousness because the Examiner has failed to establish any of the above criteria. Therefore the rejection should be withdrawn.

First, the combination of Hampton and Dempski fails to teach the claimed invention. Independent Claim 31 of the present application recites a multi-colored continuous coating layer having first and second parts of the coating layer having different coloration. Independent Claim 33 recites a multi-colored coating layer is formed by exposing one or more parts of the coating layer to irradiation. A tablet having the structural features recited in Claims 31 and 33 is not

disclosed or suggested by the cited references. Hampton teaches a multi-colored core; not a multi-colored coating. Dempski specifically teaches the use of a color stabilized dye to prevent discoloration or speckling in the film coating. As a result, a tablet utilizing the color stabilization dye of Dempski would not have a multi-colored film coating. Rather, such a tablet would have the multi-colored core of tablet of Hampton and an outer coating that is colored according to the dye that is part of the coating of Dempski. Indeed, Dempski teaches a coating that includes a dye and a compound that stabilizes the color of the coating so that the coating does not change color. See column 1, lines 44 – 56. Thus, the combination of Hampton and Demski fails to teach the claimed invention because they do not disclose a solid preparation having a continuous multi-colored film coating layer.

Further, there is no teaching or suggestion in Hampton or Dempski of how to prepare a continuous coating having two different colorations. According to Hampton, the coloring agents are contained in the first and second powders used to make the body of the tablet rather than in a coating layer. In fact, Hampton's specific description of a clear coating layer teaches away from the recited different colorations in the multi-colored coating layer. Dempski teaches that exposure to sunlight or ultraviolet light results in fading or speckling. There is no disclosure in Dempski on how to make a coating having first and second parts of different coloration or controlling the exposure of UV radiation to different parts of the coating. In contrast, the claimed invention recites that parts of the solid preparation are exposed to radiation that results in a different coloration in the part of the coating that is exposed to the radiation. As a result, the solid preparation of the claimed invention is different than the tablets of Hampton or Dempski.

Second, Dempski and Hampton fail to provide any motivation to combine their teachings. In the Office Action of April 20, 2006, the Examiner stated that it would be obvious "to incorporate the dye coating material stabilization methods, which comprise the step of exposing pills or tablets to sunlight or ultraviolet radiation taught by Dempski et al. within the multi-characterist, bi-layered, two-colored tablet of Hampton et al. if one would desire a colored change effect observed in the tablet." See page 6. However, there is no disclosure or suggestion in the prior art to provide any motivation to modify Hampton's clear coating layer and to provide differences in coloration in the coating layer. Hampton clearly teaches that the differences in

coloration arise from the core, not the outer coating. For example, Hampton teaches that the tablet includes two distinct color sections 14, 18 that form “halves of tablet core 12.” See column 3, lines 10-19 (emphasis added). Further, Hampton teaches that this colored core is coated with a clear material. See column 3, lines 15-16 and column 5, lines 37-49. Thus, nothing in Hampton’s teachings would provide motivation to effect discoloration of the coating layer because the Hampton’s core already includes the desired color variation. Indeed and as discussed in greater detail below, such modification of Hampton’s coating would be undesirable. Dempski on the other hand, clearly teaches the prevention of discoloration in the coating by using a dye stabilization compound. Thus, Dempski actually teaches how to make a tablet having a mono-colored coating layer, and does not provide motivation for producing a multi-colored tablet, let alone a multi-colored coating layer. Thus, neither Hampton nor Dempski provide any motivation that would lead one of ordinary skill in the art to combine their respective teachings.

Third, Dempski specifically teaches fading or discoloration due to ultraviolet exposure as being undesirable. Specifically, Dempski states that “[a] faded or speckled pill or tablet can have an unpleasant psychological effect...” See column 1, lines 32 – 33. Therefore, one of ordinary skill in the art would not be motivated to expose the tablet/pill of Hampton to ultraviolet light to produce a multi-colored tablet. In combining Hampton and Dempski, the Examiner has ignored the teachings in the references that teach away from the claimed invention and teach away from the combination of Hampton and Dempski. However, “[it] is improper to combine references where the references teach away from their combination.” See MPEP 2146.

Assuming for purposes of argument that there was some proper basis for combining the teachings of Hampton and Dempski, the references still fail to teach Applicants’ invention since neither Hampton alone nor Dempski alone or any combinations thereof teach a multicolored coating.

Fourth, the rejection fails to provide the required expectation of success. Moreover, the person of ordinary skill in the art would perceive just the opposite—an expectation of failure. Modifying Hampton to have the coating of Dempski would render Hampton’s tablet unsatisfactory for its intended purpose because the color stabilization dye of Dempski would prevent visualization of the multi-colored core of Hampton. As stated above, Hampton describes

a tablet having interior colored sections with a clear demarcation line between the sections. Applying the coating of Dempski to the core of Hamilton would prevent a user of the tablet from visualizing the colored sections disposed in the interior of the tablet. As a result, the tablet would be unsatisfactory for its intended purpose because the visualization of the interior colored sections is prevented. Thus, one of ordinary skill in the art would not be motivated to modify the tablet described in Hampton to have the coating of Dempski because such a modification would render Hampton unsatisfactory for its intended purpose.

Finally, the Examiner has failed to follow the standard for making an obviousness rejection as articulated by the *Supreme Court in Graham v. John Deere*, 383 U.S. 1 (1966) and in section 2141 of the MPEP. The crux of the Examiner's reasoning is articulated on page 8 of the Office Action. The Examiner states that "the prior art recognizes and teaches a tablet that is multicolored and has two layers that provide for distinct colors with different color sections, provided for easy recognition of the tablet and teaches the concept that exposure of tablets to radiation results in fading or discoloration of tablets." In other words, the Examiner is reasoning that the claimed invention is obvious because two colored tablets are known and it is known that UV radiation causes fading. This is not the proper inquiry in making an obvious rejection.

According to *Graham*, an obviousness analysis includes: (A) determining the scope and contents of the prior art; and (B) ascertaining the differences between the prior art and the claims in issue. See MPEP 2141. The Examiner has failed to do both of these. First, the Examiner has failed to understand the scope and contents of the prior art. As discussed above, Dempski teaches a dye coating that is stabilized; not a multicolored coating. Further, Dempski teaches that fading or discoloration of the coating is undesirable; this teaching was completely ignored by the Examiner. Hampton teaches a clear coating with a core that is multicolored; Hampton does not teach a multicolored coating. Second, the Examiner has failed to ascertain the differences between the prior art and the claimed invention. Hampton teaches a clear coating with a multicolor core. Dempski teaches a tablet having a coating that includes a dye to resist color fading. As noted above; neither Dempski nor Hampton teach a multicolored coating. In contrast, the claimed invention recites a tablet having a multicolored continuous coating, which is not taught in Hampton or Dempski. Thus, the Examiner has failed to compare the actual

teachings of the references to the claims.

The MPEP further states that in making an obvious rejection “the references must be considered as a whole and must suggest the desirability . . . of making the combination.” See MPEP 2141. The Examiner has also failed to adhere to this tenet of patent law. As discussed above, there are no teachings in the cited references that would motivate one to combine the coating of Dempksi with the multicolored core of Hampton, and the Examiner has failed to articulate a motivation for making such a combination. Further, the Examiner’s arguments show that he has narrowed the claimed invention down to what he perceives as the “gist” of the invention, i.e., a two-colored tablet. However, the Examiner’s analysis reasoning completely ignores the claim language and fails to consider the invention as a whole. See MPEP 2141.02. The MPEP also states that “[r]easonable expectation of success is the standard with which obviousness is determined.” See *Id.* Here again the Examiner has ignored this tenet of patent law. As discussed above the references include multiple statements that teach away from any reasonable expectation of success.

The Office Action further asserts that the Applicants have failed to demonstrate that the claimed invention has any unexpected or surprising results. However, such a demonstration is unnecessary because the Office has failed to establish a *prima facie* case of obviousness.

From the above discussion, it can be seen that the Examiner has repeatedly failed to follow the standards laid out by the Supreme Court and the MPEP in making an obviousness inquiry. A proper analysis shows that the claimed invention is neither taught nor suggested by the cited references.

Claims 18 – 20 and 45 – 47 have been rejected under 35. U.S.C. § 103(a) as being unpatentable over Hampton in combination with U.S. Patent No. 5,464,631 to Hoover et al.

Hoover describes a caplet wherein a caplet core is encapsulated in a gelatin capsule. The caplet and capsule are of two distinct colors so that the resulting caplet has two colors. Hoover further states that “[i]nsertion of the caplet within one-half of a gelatin capsule also allows for the visual perception of embossed or debossed letters, logos, symbols, and that like that may be placed on the surface of the caplet.” See column 4, lines 37-44. (emphasis added). In contrast, the patterns recited in the present claims are part of the coating and are not printed or adhered to

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the surface of the coating. This is a completely different structure than the caplet of Hoover. Thus, the combination of Hampton, Dempksi and Hoover fails to disclose or suggest the claimed invention.

Thus, Claims 31 and 33, and any claims dependent thereon are patentable over the cited references because the references fail to disclose or suggest the claimed invention, and the cited references are not properly combinable.

Conclusion

It is not believed that extensions of time or fees for net addition of claims are required, beyond those that may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 CFR § 1.136(a), and any fee required therefore (including fees for net addition of claims) is hereby authorized to be charged to Deposit Account No. 16-0605.

Respectfully submitted,

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